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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,695

09/30/2003

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ADCI-073

5085

24353 7590 07/02/2008
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EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/674,695	Applicant(s) PIERCE ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6-16, 18, 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-16, 18, 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The examiner has withdrawn the objection to the drawings in view of the newly submitted drawings of 3-4-2008.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 6-11, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (USP 6,103,033) in view of Charlton et al (USP 5,798,031). Say and Charlton are being cited and relied on for the first time with this office action. There use here was necessitated by the applicant's amendment to the claims.

4. Say discloses a biosensor for determining a concentration of an analyte in a liquid sample (e.g. glucose in blood) comprising an electrode support 50, an arrangement of electrodes (58, 60, 62) disposed on the electrode support, the arrangement of electrodes comprising at least one working electrode 58 and a second electrode (60, 62), the working electrode comprising conductive ink and at least one enzyme and mediator in it. See col. 20, ll. 10-29 where Say teaches placing the catalyst in the electrode ink and see col. 19, l. 43 - col. 20, l. 9 where Say considers the mediator to be part of the catalyst as well. Say discloses first and second conductive tracks 52 leading from the working and second electrode to an electrical contact 49. See fig. 11 for example. Say does not explicitly disclose the use of a polymer that provides a

Art Unit: 1795

hydrophilic domain. Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Say would inherently create hydrophilic domains in the conductive ink.

5. With respect to the mediator composition, the osmium complexes of col. 19, ll. 12-33 for example read on the defined organometallic and organic compounds of the claims.

6. With respect to the use of small sample volumes, see Say, col. 4, ll. 8-14.

7. With respect to the electrode spacing, see Say col. 11, ll. 22-36.

8. With respect to the electrode area, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize electrode areas of from 0.5 mm² to 5 mm², since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In particular, larger electrodes would provide greater sensitivity while smaller electrodes would hold the overall size of the sensor down. Finding the appropriate area that balances these competing concerns requires only routine skill in the art.

9. With respect to the presence of a third or trigger electrode, Say discloses a third electrode 62 (col. 14, ll. 44-50) and this would read on the defined third electrode. Although not disclosed as being a trigger electrode, the term “trigger” merely defines how applicant intends to utilize the electrode and does not further define the structure of the electrode itself.

Art Unit: 1795

10. With respect to the set forth fourth electrode, see Say fig. 6 and col. 14, ll. 29-43. With respect to the electrode having a trigger function, this again defines how the electrode is to be used and doesn't further define the structure of the electrode itself.
11. With respect to the use of dehydrogenase, see Say col. 19, ll. 43-55.
12. With respect to claim 31 (those limitations not covered above), Say discloses that the biosensor can be made to contact a meter (i.e. control unit). See col. 13, ll. 28-40.
13. Claims 1, 3, 6-16, 18 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and Charlton.
14. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21, ll. 28-31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into a conductive ink. Say (who has the same assignee as Feldman) discloses that in an effort to minimize leaching of the catalysts (i.e. the enzyme and mediator) can be incorporated directly into the conductive ink of

Art Unit: 1795

the sensor. See col. 19, l. 56 - col. 20, l. 29, especially col. 20, ll. 10-29. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Say for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. Keeping the mediator and enzyme from leaching away was a particular concern of Feldman (see abstract for example) and the suggestion of incorporating the enzyme and mediator into the conductive ink by Say represents an alternate or additional way to prevent such a leaching from occurring.

15. Neither Feldman nor Say explicitly disclose the use of a polymer that provides hydrophilic domains in the conductive ink, Charlton discloses that the enzyme can be deposited down onto an electrode in the presence of a hydrophilic polymer, which would increase the hydration access to the enzyme itself. See col. 1, ll. 51-59 and col. 2, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Charlton for the sensor of Feldman and Say so as to increase the hydration properties of the electrode thereby permit adequate sample exposure to the enzyme. The addition of a hydrophilic polymer to the conductive ink of Feldman and Say would inherently create hydrophilic domains in the conductive ink.

16. With respect to the various dependent claim limitations, see the discussion of Feldman and these limitations in the office action of 6-29-2005.

17. With respect to new claim 31 (those limitations not previous covered), Feldman teaches the use of a meter that contacts the leads of the sensor. See col. 35, ll. 27-61.

Art Unit: 1795

18. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say in view of Charlton as set forth for claims 1 and 31 above, and in further view of Yamashita et al (USP 5,472,590).

19. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Say and Charlton as set forth for claims 1, 16, and 31 above, and in further view of Yamashita. Yamashita is being cited and relied on for the first time with this office action. Its use here was necessitated by new claims 32-34.

20. The references set forth all the limitations of claims 32 and 34 (for Say in view of Charlton) or claims 32-34 (for Feldman in view of Say and Charlton), but did not explicitly recite the use of polyethylene glycol as the hydrophilic polymer. However, polyethylene glycol is a subset of the broader polymer class of polyethylene oxide utilized by Charlton. In particular, polyethylene glycol is polyethylene oxide where the terminal groups of the polymer are hydroxyl units. Yamashita explicitly teaches that polyethylene glycol is a particular useful choice of polyalkylene oxide polymer when the property being desired is a hydratable substance (i.e. “water-keeping property”). See abstract and col. 5, ll. 51-63 of Yamashita. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the polyethylene glycol as taught by Yamashita for the polyethylene oxide suggested by Charlton for the biosensor of Say and Charlton or Feldman, Say, and Charlton because polyethylene glycol has been demonstrated as being a suitable choice of hydratable polyethylene oxide for sensor applications.

Response to Arguments

21. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
July 2, 2008